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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/691,968

10/24/2003

Alan Smith

15407.105061

6975

20786

7590

12/28/2009

KING & SPALDING

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EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

12/28/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/691,968	<b>Applicant(s)</b> SMITH ET AL.	
	<b>Examiner</b> THEODORE J. STIGELL	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,7-40,76-79 and 82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7-40,76-79 and 82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/1/2009 has been entered.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 7-40, 76-70, and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eppstein et al. (6,022,316) in view of Eppstein et al. (6,692,456).

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Eppstein '316 discloses a method of delivering drugs through and/or withdrawing fluids from a biological membrane comprising the steps of applying at least one heated probe element (210, 212) capable of delivering thermal energy to cause ablation of the membrane to form a plurality of openings wherein the depth of the micropores preferably ranges from 40-180 microns (see column 4, lines 62-65).

Eppstein '316 does not specifically teach to include a step of delivering the drug by placing a patch on the openings.

Eppstein '456 discloses a method of delivering drugs through created micropores by placing a patch on the skin (see Example 6a, Passive Vaccine Delivery Device).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Eppstein '316 with the step of patch drug delivery as disclosed by Eppstein '456 as such a step is a useful equivalent of delivering drugs through micropores.

Furthermore, although Eppstein '316 teaches a preferable range of openings between 40 and 180 microns, Eppstein '316 does not specifically teach that "an opening depth of the majority of said delivery openings falls with a range between about 40 and about 90 microns" as is recited in claim 1 or "said delivery openings have a distribution resulting in a bell-shaped curve with said delivery openings having a mean opening depth of between about 40 and 90 microns" as is recited in claim 21. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the openings with the recited distribution, since it has been held that where the

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general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955). One of ordinary skill in the art would understand that different micropore depths are needed depending on the type of drug delivered and the type of condition being treated. Once a user determines the optimum depth needed, only routine skill is involved in creating a micropore or group of micropores with that depth. One of ordinary skill would appreciate that adjusting the current, the pulse duration, the pulse shape, or the shape of the heated probe element will allow the user to adjust the size and depth of the micropore.

### ***Response to Arguments***

Applicant's arguments filed 10/1/2009 have been fully considered but they are not persuasive.

In response to the applicant's arguments that the combination of Eppstein '316 and Eppstein '456 does not teach the recited limitations, the examiner respectfully disagrees. The applicant argues that the general conditions of the pending application are not disclosed in the '316 patent in that the range of the micropore depths of the '316 patent are for the purposes of electrically coupling first and second electrodes to the micropores which is then followed by electroporation and delivery of a substance. In other words, the '316 patent teaches using the micropore depth for electroporation and delivery while the present application teaches micropore depth for delivery without the need for electroporation. The examiner contends that the breadth of the claims does not prohibit electroporation from being used in combination with the heated probe.

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Ultimately, the '316 patent teaches the general conditions of the claims which is applying a heated probe to a membrane in order form a plurality of openings between about 40 and 180 microns deep. It would then be within the skill of the ordinary artisan to discover the optimum range.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Theodore J Stigell/  
Examiner, Art Unit 3763